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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,386	07/01/2003	Sudershan K. Arora	RLL-9.2US	1529
7590	03/10/2004			
Jay R. Deshmukh Ranbaxy Pharmaceuticals, Inc. Suite 2100 600 College Road, East Princeton, NJ 08540			EXAMINER KHARE, DEVESH	
			ART UNIT 1623	PAPER NUMBER
DATE MAILED: 03/10/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/611,386

Applicant(s)

ARORA ET AL.

Examiner

Devesh Khare

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 5 and 6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12-29-2003</u> . | 6) <input type="checkbox"/> Other: ____ |

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Claims 5 and 6 are currently pending in this application.

Objection

A period is missing at the end of claim 5.

An appropriate correction is required.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **5 and 6** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "a suitable isocyanate and in a suitable solvent" and "low temperature" in claim 5, are relative terms, which render the claim indefinite. The terms "a suitable isocyanate and in a suitable solvent" and "low temperature" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

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35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arora et al.(Arora) (U.S. Patent #5,637,570) in view of Bouveng (Acta. Chem. Scand. 1961, 15, 96-100).

Claims **5 and 6** are drawn to a process for preparing compounds of Formula I by treating the compound of Formula II with an isocyanate in a solvent at low temperature. Additional claim limitations include the substituent R₂ is –NH(CH₂)_n-pyrrolidinyl, -piperidinyl, -morpholinyl or -hexamethyleneimino.

Arora teaches a process for the preparation of the 2,3-O-isopropylidene- α -L-xylo-2-hexulofuranose compounds wherein the hydroxyl group at C-4 is substituted with a nitrogen containing heterocyclic moiety (abstract). Arora discloses that the said compounds exhibit greater potency for cancer treatment and provides ease of oral administration when the 4-OH is substituted with nitrogen containing heterocyclic moiety (col. 2, lines 49-60). Arora discloses the preparation of 2,3-O-isopropylidene- α -L-xylo-2-hexulofuranose compounds wherein substituent R₂ is –NH(CH₂)_n-pyrrolidinyl, -piperidinyl, -morpholinyl or –hexamethyleneimino (cols. 4-6, scheme 1 and the

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compounds in cols. 7-8). Arora differs from the complete scope of the applicants invention in that Arora does not disclose the preparation of the 2,3-O-isopropylidene- α -L-xyllo-2-hexulofuranose compounds wherein the free hydroxyl group at C-4 is treated with an isocyanate reagent to produce a nitrogen containing heterocyclic moiety such as carbamate. It is noted that there is no function of the carbamate group is given in the specification as originally filed. An undisclosed advantage is given little or no weight.

Bouveng teaches a process to make the phenylisocyanate derivatives of carbohydrates, wherein a phenylisocyanate reagent in dimethylformamide solvent is used to transform free hydroxyl groups to a carbamate groups (see abstract and experimental on page 98, last para.).

It would have been obvious to person having ordinary skill in the art at the time the invention was made, to modify the process for conversion of the 4-hydroxy group to its corresponding nitrogen containing heterocyclic moiety of Arora in view of the teachings of Bouveng to a process of conversion of a free hydroxyl group to its corresponding carbamate by treating with an isocyanate reagent because Arora discloses that the said compounds exhibit greater potency for cancer treatment and provides ease of oral administration when the 4-OH is substituted with a nitrogen containing heterocyclic moiety (col. 2, lines 49-60).

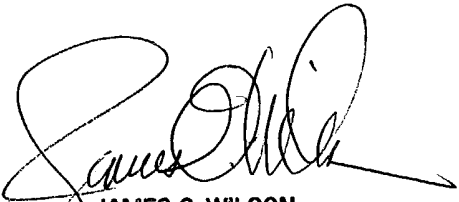
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D., JD(3Y).
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March 5, 2004



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600